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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,653	08/05/2003	Randall Lashinski	PVI-5813CP2CP1CP1CON2	6365
30452	7590	07/23/2008		
EDWARDS LIFESCIENCES CORPORATION			EXAMINER	
LEGAL DEPARTMENT			MATTHEWS, WILLIAM H	
ONE EDWARDS WAY			ART UNIT	
IRVINE, CA 92614			PAPER NUMBER	
			3774	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/634,653

Applicant(s)

LASHINSKI ET AL.

Examiner

William H. Matthews (Howie)

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6 and 12-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-30 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 12, 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1,2,3,6,12 and 31-40 have been considered but are not persuasive. Applicant states Solem lack a forming element which is advanced distally thereby changing curvature of the implant. Examiner disagrees because paragraph 51 describe a distal movement of the forming element 13/15 thereby causing change in curvature of the implant (upon release, see figures 5-6).

Applicant's arguments with respect to claims 13-30 in view of Alferness are persuasive and the previous rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 12, and 31-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Solem et al. US 2001/0018611 ("Solem").

Solem disclose in figures 2-6 and paragraphs 0048-0051 a system for remodeling the mitral valve annulus comprising a catheter and implant 8 having a first

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configuration (figure 5) and second remodeling configuration (paragraph 0050 when the sheath is retracted allowing hooks to penetrate tissue), and the catheter includes a control mechanism for selectively adjusting curvature (figure 6 where catheter 21 presses blades 18 causes arms 13 to move distally to release the implant). The remodeling configuration comprises an arc (figure 3) and the device may include a coating (paragraph 0070). Rod 15 (and arms 13) is readable upon the flexible member of claim 12 because the proximal end is attached to control mechanism 17,18 and the distal end 13 is attached to the distal end of the implant 8.

Note the limitations of lines 9-13 and the final 3 lines of claim 1, as well as claims 39-40 entirely, describe intended use recitations. According to MPEP 2114, functional language or intended use recitations do not necessarily structurally distinguish from the prior art. Anticipation exists if the prior art meets the claimed structure and is capable of the function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. US 2001/0018611 as described above with respect to claim 1.

Solem meets the structural limitations of claim 3 as described above but lack the express written disclosure of a radius within the range of about 10-20mm. However, Solem is directed towards remodeling of a mitral valve annulus similar to that as applicant's device and each appear to show arcs having the claimed radii. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to select a device curvature of about 10-20mm in order to treat a particular patient's annulus deficiency.

Allowable Subject Matter

Claims 13-30 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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